

A Review on Adverse Drug Reaction Monitoring and Current Status of Pharmacovigilance Activities in India

Vamsi Danyasi^{*1}, Lokesh Naik², Sreenadh Reddy³

¹Assistant Professor, Department of Pharmacology, Raghavendra Institute of Pharmaceutical Education and Research (RIPER), Anantapur - 515721, Andhra Pradesh

²Medical writer, Crixus communication Pvt. Ltd, Bengaluru

³Assistant Professor, Sun Institute of Pharmaceutical Education & Research, Kakupalli, Andhra Pradesh-524346

***Corresponding E-mail:** danyasivamsi@gmail.com

Received: 16-03- 2026 | Revised: 24-04- 2026 | Accepted: 24-05- 2026 | Published: 13-07-2026

ABSTRACT

Pharmacovigilance is the science and activities relating to the detection, assessment, and prevention of adverse effects or any other possible drug-related problems, including herbal medicines. Adverse drug reactions (ADR) is one of the common causes of prolonged hospitalization and death among patients. Pharmacovigilance plays a key role in the surveillance of adverse drug reactions. Around 10% of hospital admissions are estimated to be due to ADRs and about 5-20% of hospitalized patients experience a serious ADR. Pharmacovigilance plays a prominent role in establishing the safety profile of marketed drugs pharmacovigilance is an important and integral part of the safe practice of medicine. Only a small proportion of the ADR are reported to the central monitoring center. Most of the ADR's go unrecognized in the guise of a disease or a symptom of a disease. Spontaneous reporting is a method of ADR identification that relies on healthcare professionals to identify and report suspected ADRs. The major limitation of this method is under-reporting. Patient reporting of ADRs aims to increase the number of reported ADRs and is, therefore, another way to improve treatment safety. Hence there is a need for better reporting of ADRs and the creation of a database that allows feedback and drug alerts by the central agency (PvPI) and better management of patients. Causality assessment is the method by which the extent of the relationship between a drug and a suspected reaction is established. The majority of ADRs were probable in causality and moderate in severity. However, the preventability assessment was a challenge for the data of this study. There is a necessity to increase awareness of the importance of ADR reporting among healthcare professionals must be followed.

Keywords: Pharmacovigilance, ADRs, Healthcare professionals, Spontaneous reporting, PvPI

INTRODUCTION

Pharmakon (Greek) denotes drug, Vigilare (Latin) represents to keep watch; awake, alert; watchfulness in respect of care, danger, caution, circumspection; process of paying close and continuous attention. According to the Pharmacovigilance definition given by WHO, it is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems. Recently, its concerns have been widened to include herbals, traditional and complementary medicines, blood products, biological, medical devices and vaccines.

Pharmacovigilance has been defined as the process of identifying and responding to drug safety issues and has grown considerably as a discipline over the past 10 to 15 years. Pharmaceutical companies are international, hence the number of staff working in this field within the industry, particularly in other European countries and the USA, is far greater. A major pharmaceutical company such as Astra has over 100 permanent, experienced staff in pharmacovigilance within its research and development organization in Sweden and the UK and a similar number in local operating companies worldwide. This development has been driven by an increased recognition of the role of pharmacovigilance, the investigation and marketing of a

wider range of diverse medicinal products and more stringent and detailed regulatory requirements [1-3].

Types of Adverse drug reaction

Type A (Augmented): Common, predictable, and dose-related. These occur when a drug's normal pharmacological effect is too strong. Examples: Bleeding from blood thinners like warfarin, or low blood pressure from anti-hypertensive. Type B (Bizarre): Uncommon, unpredictable, and dose-independent. These are idiosyncratic reactions that are not related to the drug's primary pharmacological actions. Examples: Anaphylaxis (severe allergic reactions) to penicillin or severe skin rashes. Type C (Chronic): Dose- and time-related. These occur due to long-term, cumulative exposure to a medication. Examples: Bone loss (osteoporosis) from prolonged use of corticosteroids. Type D (Delayed): Time-related. These reactions occur days, weeks, or even years after taking the medication. Examples: Birth defects (teratogenicity) or the development of cancer due to prior drug exposure.

Type E (End-of-Use):

Withdrawal. These occur when a medication is stopped abruptly. Examples: Rebound hypertension from suddenly stopping a blood pressure medication. Type F (Failure): Failure of therapy. These are unexpected failures of the medication to work as intended, often caused by drug interactions. Examples:

Oral contraceptives failing to work due to interactions with certain antibiotics or anti-seizure drugs [4-5].

Pre-marketing clinical trials

Safety monitoring in clinical trials involves collecting adverse events, laboratory investigations and details of the clinical examination of patients. Pharmacovigilance staff may be involved to varying degrees in all phases of clinical trials, including the planning, execution, data analysis and reporting of safety information. Safety issues from animal pharmacology and toxicology studies, findings in phase I studies, known ADRs with similar drugs, signals from other studies and special patient groups, (e.g. the elderly) need to be addressed. The practice of collecting all adverse events rather than suspected ADRs arose from the failure of clinical trials to detect serious reactions with prazosin and after several years of experience this is now the approach adopted by companies in most studies.

Visibility, communication, and feedback of PVPI

A website created by CDSCO is dedicated to PVPI. In phase II of the program, there is a provision for online reporting of ADRs by healthcare professionals who are not covered under the program. The CDSCO headquarters, in collaboration with NCC, published a quarterly "Medicine Safety Newsletter" comprising 4-16 pages. Approximately 3000 copies will be printed for circulation to healthcare institutions across the nation. A Medicine Safety Card has been included in the Medicine Safety Newsletter, and in national medical journals, to ensure that healthcare professionals not covered under the program can report ADRs directly to any of the centers. These are creating awareness about the program and ensure reporters get adequate feedback and remain motivated. In addition, to enhance the awareness and visibility of the programme, focused workshops, symposia, and group meetings on ADR reporting and causality assessment are carried out at regular intervals by all the centers [6-7].

Guidelines of PVPI

Globally, many countries have formulated their own PV guidelines with the aim of having a systematic process of safety reporting. The ICH has six guidelines pertaining to various aspects of drug safety. E2A- Clinical Safety Data Management: Definitions and standards for expedited reporting, E2B- Clinical Safety Data Management: Data elements for transmission of individual case safety reports, E2C- Clinical Safety Data Management: Periodic safety update reports for marketed drugs, E2D- Post-Approval Safety Data Management: Definitions and standards for expedited reporting, E2E-Pharmacovigilance planning, and E2F- Development Safety Update Report. Hence, legislative requirements of PV in India are guided by specifications of Schedule Y of the Drugs and Cosmetics Act 1945. Schedule Y also deals with regulations relating to pre-clinical and clinical studies for development of a new drug, as well as clinical trial requirements for import, manufacture, and obtaining marketing approval for a new drug in India. Schedule Y was revised and amended on 20 January 2005 as a continued commitment of the drugs controller general of India (DCGI) to ensure adequate compliance of PV obligations of pharmaceutical companies. An attempt has been made in the amended Schedule Y to better define the roles and responsibilities of pharmaceutical companies for their products, as well as relating to reporting of AEs from clinical trials. India has only a small section of Schedule Y dedicated to drug safety, International Journal of Research in Pharmacy and Life Sciences

which when viewed in light of contemporary global practice, seems to have many lacunae. There is thus a felt need that CDSCO must formulate detailed PV guidelines.

The signal generation process

Signals may be generated through four different methods: spontaneous reporting, published case reports, cohort studies and post-marketing clinical trials.

Spontaneous reporting

Recording and reporting clinical observations of a suspected ADR with a marketed drug is known as spontaneous or voluntary reporting. The national system in the UK is the 'yellow card' scheme where doctors, dentists, and recently, hospital pharmacists are encouraged to report all suspected reactions to new medicines and serious suspected reactions to established medicines. Pharmaceutical companies also collect and collate such reports with their licensed products. Reports to companies often come initially as a question from a prescribing physician or pharmacist to Medical Information or a sales representative about whether a product could be the cause of a patient's problem. After providing such information, pharmacovigilance staff will seek details of the case to add to the database of reports, this relies on the goodwill and continued interest of reporters. Companies must report suspected ADRs to the MCA and other authorities; some authorities, including MCA, make anonymized data available to license holders [8-9]. Spontaneous reporting has advantages in that it is available immediately a new product is marketed, continues indefinitely and covers all patients receiving the drug. It is the most likely method of detecting new, rare ADRs and frequently generates safety signals which need to be examined further. The main limitations are the difficulty in recognizing previously unknown reactions, particularly events that are not usually thought of as being ADRs and under-reporting, which is variable, sensitive to reporting stimuli and difficult to quantify. It usually does not confirm hypotheses, although situations exist where spontaneous reporting data alone allow conclusions that a signal indeed represents a true ADR report.

Published case reports

Publishing case reports of suspected ADRs in medical journals is an established way of alerting others to possible drug hazards. However, it has limitations as only a very small proportion of cases can be published, reports are sometimes poorly documented, publication depends on editorial selection and there is often considerable delay between occurrence and publication. Companies and some regulatory authorities actively monitor the published literature for such reports. This will involve screening key journals where ADRs are described, monitoring publications such as 'Reactions Weekly' (ADIS International) and running regular standard searches on databases such as Medline and Excerpta Medica. With efficient regulatory and company safety surveillance it is now relatively rare for a new ADR to be signaled primarily through published cases, however, publication of well characterized ADRs still fills an important function in alerting physicians. A more recent development is reports of possible ADRs appearing on the Internet and many companies are still determining how they should best handle them.

Cohort studies

Companies may set up or sponsor prospective, non-interventional cohort type studies either to answer safety

questions raised after marketing or as a general hypothesis generating and testing tool to be used as need arises. In the past, company sponsored studies were considered poor at detecting new safety issues mainly because of slow recruitment and lack of control groups. Since 1994 such studies in the UK have been subject to the SAMM (Safety Assessment of Marketed Medicines) guidelines which have ensured a closer dialogue between companies and the MCA. Generally, cohort studies are ineffective as tools for signal generation, mainly because of limitations in size, also data from such studies are subject to the 'signal vs noise' problem in the same way as spontaneous reports [10-11].

Post-marketing clinical trials

Large randomized clinical trials with wide entry criteria (similar to SPC indications) can be valuable in assessing the safety of marketed products as well as confirming efficacy. Because patients are randomized to different treatments they do not have some of the problems inherent in cohort studies, for instance whether the control group is truly comparable. Companies can choose to set up or sponsor such studies to address particular safety issues. To make them sufficiently large to provide more information than the trials performed for product registration purposes may make them prohibitively expensive, hence a simple protocol and study plan with limited observations is desirable.

Hypothesis testing process

A typical situation in company pharmacovigilance is that a small number of reports have been received, showing that the patients have developed a serious medical condition, e.g. liver function disturbance, convulsions or blood dyscrasia, while receiving a particular product. As much detail as possible on the cases must be obtained and any new cases followed-up rigorously but the hypothesis must be raised that this condition has been caused by the drug, i.e. represents an ADR. For analysis of this question, a number of approaches can be taken, the most common being to use the spontaneous reporting data in a variety of ways.

Using spontaneous reporting data for hypothesis testing

It is commonplace in clinical practice to make decisions and take actions based on assessment of causality between an event and a certain drug in individual cases. General pharmacovigilance experience however, is that determination of causality in individual cases has a high degree of uncertainty. Attempts to develop the methodology for causality assessment, e.g. by using a Bayesian approach have yielded interesting results but has so far had little impact. Some exceptions to this uncertainty exist, however, for instance the situation of positive rechallenge, i.e. that symptoms and objective findings, having disappeared following discontinuation of the treatment, reoccur on renewed exposure. The other situation is when the adverse event in several patients shows a very consistent pattern both in symptomatology and in relation to the duration of treatment before symptoms, e.g. zimeldine and Guillain-Barre syndrome [12-13]. These points illustrate an important similarity between clinical medicine and pharmacovigilance there is no substitute for careful observation and analysis of single cases. In special situations, various biochemical markers or pharmacokinetic data in individual patients may also contribute to judgements regarding whether observed symptoms or disorders constitute an ADR.

International Journal of Research in Pharmacy and Life Sciences

Historical Background of Pharmacovigilance:

In 1986 that a formal adverse drug reaction (ADR) monitoring system consisting of 12 regional centers, each covering a population of 50 million, was proposed for India.² In 1997, India joined hands with the World Health Organization (WHO) Adverse Drug Reaction Monitoring Program based in Uppsala, Sweden. Three centers for ADR monitoring were identified, mainly based in teaching hospital: A National Pharmacovigilance Centre located in the Department of Pharmacology, All India Institute of Medical Sciences (AIIMS), New Delhi and two WHO special centres in Mumbai (KEM Hospital) and Aligarh (JLN Hospital, Aligarh Muslim University).

These were center to report ADRs to the drug regulatory authority of India. The major role of the center was to monitor ADRs to medicines which are marketed in India. However, they hardly functioned as information about the need to report ADRs and about the functions of this monitoring center were yet to reach the prescribers and there was lack of funding from the government. This attempt was unsuccessful and hence, again from the 1st of January 2005, the WHO- sponsored and World Bank-funded National Pharmacovigilance Program for India was made operational. The National Pharmacovigilance Program established in January 2005, was to be overseen by the National Pharmacovigilance Advisory Committee based in the Central Drugs Standard Control Organization (CDSCO), New Delhi.

The pharmaceutical industry has prime responsibility for the safety of medicines, from the start of drug development and thereafter throughout the lifetime of the drug. Many companies have developed innovative and efficient monitoring systems that have contributed to the detection of new safety signals. Encouraged by the 1998 Erice Declaration on Communicating Drug Safety, communication and exchange of information between the industry, regulatory authorities and the public has improved, which has more recently been further supported by the establishment of the community database (Eudravigilance Database) in December 2001, in London [14-15].

National and international regulatory requirements for Pharmacovigilance

The reporting of safety information from clinical trials and with marketed products by pharmaceutical companies to regulatory authorities has been mandatory for many years but with each national authority having different requirements. Recent attempts have been made to unify reporting under the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) which brings together regulatory authorities and other experts from Europe, USA and Japan. However, despite this and European Directives and Regulations there is still diversity in requirements and the guidance from the CPMP Pharmacovigilance Working Party is still in preparation. The current UK requirements for investigational drugs are included in the CTX/CTC guidance and for licensed products are outlined in the MCA publication Medicines Act Information Letter No 87. For marketed products individual serious suspected reactions (expedited reports) must be sent to MCA within 15 calendar days of receipt by the company. This applies to UK

cases and those from all other European member states; for cases originating outside the EU only serious and unexpected cases (those not listed in the SPC) are subject to expedited reporting. Periodic safety updates containing information on a much wider range of reports and other worldwide safety data over a specified time period are also required. Other EU countries have similar requirements but often differ in detail. If the product is being developed or is marketed in the USA there are extensive FDA reporting regulations with strict deadlines that also have to be met.

One feature of the European requirements is that Marketing Authorization holders i.e. companies, must have a suitably qualified person responsible for pharmacovigilance. Their responsibilities include the establishment and maintenance of a system which ensures that all ADRs reported to company personnel are collected and collated so that they may be accessed at a single point within the community, the preparation of various reports and answering requests for the provision of additional information from the authorities [16-17].

Constituted pharmacovigilance program of India

The Pharmacovigilance Program of India (PvPI) is deeply rooted in the legal framework provided by the Drugs and Cosmetics Act of 1940 and subsequent Drugs and Cosmetics rule of 1945. This Regulatory structure places the program under the jurisdiction of the Central Drugs Standard Control Organization (CDSCO), which is India's apex regulatory body for pharmaceutical and medical devices.

PvPI has several key objectives, with a primary focus on monitoring adverse drug reactions to ensure patient safety. The National Coordinating Centre serves as the central coordinating body, responsible for overseeing the program's functioning. It plays a pivotal role in receiving ADR reports from diverse sources, including healthcare professionals, consumers, and pharmaceutical companies. To facilitate efficient data collection and analysis, Regional Adverse Drug Reaction Monitoring Centre's (AMCs) are strategically located across the country. These AMCs act as regional hubs, processing ADR reports and forwarding relevant information to the NCC.

The reporting mechanism are designed to be accessible to various stakeholders, including an online platform established by the CDSCO, making it user- friendly for healthcare professionals and the public alike. Signal detection and analysis form a critical component of PvPI's activities. Systematic evaluation, incorporating both statistical and clinical assessments, is employed to identify potential safety signals associated with pharmaceutical products. This rigorous approach ensures that emerging risks are promptly recognized and addressed. PvPI also emphasizes communication and dissemination of safety information. Regular newsletters, safety alerts, and educational programs are employed to raise awareness among healthcare professionals and the broader public. This proactive public. This proactive approach contributes to informed decisions-making and supports a culture of safety within the healthcare community.

Drug Controller General of India

The Drug Controller General of India (DCGI) is the regulatory authority in India responsible for the approval of International Journal of Research in Pharmacy and Life Sciences

Pharmaceuticals including drugs and medical devices. Its role in pharmacovigilance involves monitoring and assessing the safety of drugs post- marketing. It ensures that pharmaceutical companies comply with safety regulations and investigates adverse drug reactions reported by healthcare professionals and consumers.

The history of DCGI traces back to the formulation of the Central Drugs Standard Control Organization (CDSCO) in 1940. Over the years, CDSCO evolved, and in 1961, the Drugs and Cosmetics Act was enacted, empowering the organization to regulate the import, manufacture distribution, and sale of drug. The pharmacovigilance Program of India (PvPI) was established in 2010 under the aegis of CDSCO and DCGI. PvPI aims to collect, monitor, analyze adverse drug reactions (ADRs) to enhance drug safety in India. It collaborates with the world Health Organization (WHO) to contribute ADR data to the global database. DCGI's involvement in pharmacovigilance signifies India's commitment to ensuring the safety and efficacy of Pharmaceuticals, emphasizing continual monitoring and evaluation even after a drug is in the market.

Functions of DCGI

The Drug Controller General of India (DCGI) plays a crucial role in pharmacovigilance by overseeing various aspects of drug regulation, safety, and surveillance.

Regulatory Approval:

DCGI is responsible for granting approval for new drugs, ensuring they meet safety, efficacy, and quality standards before they enter the Indian market. This involves evaluating clinical trial data submitted by pharmaceutical companies.

Clinical Trial Oversight:

DCGI regulates and monitors clinical trials conducted in India ensure ethical practices Patient safety, and adherence to regulatory protocols. WPost Marketing Surveillance: After a drug is approved and available in the market, DCGI continues monitoring it for any adverse effects or safety concerns reported through pharmacovigilance systems. This involves analyzing and assessing adverse event reports submitted by healthcare professionals, patients, and pharmaceutical companies. Quality Control: DCGI ensures that drugs in the market comply with established quality standards by inspecting manufacturing facilities, reviewing production processes, and regulating the import of Pharmaceuticals. Enforcement of regulations: DCGI enforces regulations and guidelines related to drug manufacturing, labeling, distribution, and marketing to maintain public safety standards. Overall, DCGI's functions in pharmacovigilance are centered around safeguarding public health by regulating the entire lifecycle of pharmaceutical products, from approval to post- marketing surveillance, ensuring their safety, efficacy, and quality.

Central Drugs Standard Control Organization (CDSCO)

The Central Drugs Standard Control Organization (CDSCO) in India, overseen by the Directorate General of health services, ministry of health and family welfare, regulates and controls the manufacture, distribution, and sale of drugs and Cosmetics. It functions through various collaborations and authorities such as the Drug Technical Advisory Board, Drugs Consultative Committee, and Central Drug Laboratories. CDSCO manages approval processes for new medicines, conducts clinical trials, establishes prescription regulations, monitors Drug efficacy and

maintenance uniformity in administering the Drugs and Cosmetics Act. Additionally, it collaborates with State Drug Control Organizations to ensure proper regulation and supervision at the state level, including authorizing drug testing facilities, regulating drug production and marketing, and overseeing the manufacturing process of drug within the state.

This comprehensive regulatory structure, established under the 1940 Drug and Cosmetics Act and 1945 Drug and Cosmetics Act 1945 rules, involves both Central and state agencies working together to maintain the quality and safety of Pharmaceuticals in India.

Abbreviated New Drug Application

The Abbreviated New Drug Application (ANDA) is submission to the FDA for the approval of generic drugs. It allows a manufacturer to produce a generic version of an already FDA-approved drug once its patent or exclusivity period expires. An ANDA demonstrates that the generic drug is bioequivalent to the brand-name drug, ensuring it has the same active ingredient, strength, dosage form, route of administration, and performance characteristics [18].

Functions of ANDA

The Abbreviated New Drug Application (ANDA) plays a crucial role in pharmacovigilance by ensuring the safety and efficacy of generic drugs.

Regulatory submission:

AANDA is submitted to regulatory authorities (e.g. FDA in the United States) to seek approval for marketing a generic version of an already approved reference drugs. This involves comparative studies to establish similar pharmacokinetic parameters.

Pharmacovigilance Data:

Submission includes pharmacovigilance data, addressing the safety and adverse reactions associated with the generic drug. This involves reporting any adverse events observed during clinical trials or post-marketing surveillance.

Post-Marketing surveillance:

Once approved, post-marketing surveillance continues to monitor the generic drug's safety and efficacy. Pharmacovigilance activities involve collecting, analyzing, and evaluating adverse drug reactions (ADRs) and other safety-related information.

Safety Reporting Obligations:

ANDA holders have obligations to promptly report any new safety information to regulatory authorities. This includes updates on known risks, emerging safety concerns, and any changes in the benefits-risks profile.

Risk Management plans (RMP):

If necessary, an ANDA may include a risk management plan to outline strategies for identifying, characterizing, preventing and minimizing risks associated with the generic drug.

Analysis: Continues monitoring for potential safety signal involves the Analysis of various data sources, such as spontaneous reports, literature, and clinical studies.

Agencies:

ANDA holders collaborate with regulatory agencies to address safety concerns and implement any necessary changes to the drug's labeling or prescribing information.

Reports:

Submission of PSURs is required to provide of the generic drug at defined intervals.

Recall and Market Withdrawal: If serious safety concerns arise, the ANDA holder may need to initiate drug recalls or market Withdrawals in collaboration with regulatory authorities.

New Drug Application (NDA)

The new drug application (NDA) process is a pivotal and multifaceted stage in bringing a new pharmaceutical product to market in the United States. It begins with extensive preclinical testing, encompassing laboratory experiments and animal studies, aimed at understanding the drug's safety profile and potential efficacy. Following successful preclinical outcomes, the sponsor files an Investigation New Drugs (IND) application with the FDA, providing detailed data from preclinical studies and proposing protocol for clinical trials.

Future of Pharmacovigilance

Pharmacovigilance in the industry will continue to grow and develop as a discipline. In the past, pharmacovigilance units have spent substantial proportions of their time reporting single cases to regulatory authorities around the world, fulfilling widely different local requirements. Current developments promise that this aspect will be gradually simplified. The strong development towards international harmonization will result in much more uniform international requirements and the very rapid developments in electronic communication will allow automated distribution of case reports within companies and to regulatory authorities. The future focus of pharmacovigilance work will, therefore, be on the science more than on the formal regulatory aspects, although these, obviously, will continue to be important. Developing and using tools from, for instance, epidemiology and health economics will allow much better judgements of the real impact of treatments on public health and the costs of health care. This fits well with the increasing demand from governments, health care providers and institutional buyers regarding documentation of real benefits of treatments with acceptable risk profiles. The challenge to those working in pharmacovigilance will therefore be to investigate and document, in epidemiological and health economic terms, whether drug safety profiles obtained from clinical trials in narrowly selected populations still hold true when drugs are used in clinical practice.

Haemovigilance programme in India

Haemovigilance is the ongoing process of gathering and analyzing data on adverse responses to blood transfusions in order to understand what causes them, what happens when they do, and how to stop it from happening again. As part of the PVPI, IPC and the National Institute of Biological Sciences (NIB) in Noida have started the Haemovigilance Programme of India (HVPI), which has two major goals. To assess adverse reactions/events and their frequency related to the delivery of blood products and transfusions, first, and to assist in identifying trends, best practices, and interventions needed to enhance patient care and safety while lowering total healthcare costs, second. To guarantee patient safety during and after a blood transfusion, transfusion reactions (TRs) must be identified and managed. Acute transfusion responses (ATRs) and delayed transfusion reactions are two categories that each encompasses several subtypes of transfusion reactions. At the onset of the response, it might be challenging to categorize different ATRs because they all exhibit similar signs and symptoms.

Clinical trials in India

India has become a favorite location for clinical trials for international pharmaceutical firms as a result of the country's very appealing clinical research environment and prospects. India provides several benefits for conducting clinical trials, including the following: Availability of well qualified, English speaking research professionals including physicians. Thorough adherence to international standards, including those set forth by the US Food and Drug Administration and the International Conference on Harmonization (ICH)/World Health Organization Good Clinical Practice (ICH-GCP). Ongoing support and cooperation from the government [19].

ADR data flow

ADR reports were collected at the AMC by the PV staff who checked for validity of the report and conducted provisional causality assessment. The ADR forms are then dispatched to the coordinating center. The AMC staff maintains a log of all the activities of the center and the selected AMCs also carry out focused ADR monitoring of drugs as per the watch list. The coordinating centers are conducting causality assessment and upload the reports into the PV database. The coordinating center also prepare a consolidated report of ADRs collected at defined time intervals and then implement and integrate PV activities into public health programs involving mass usage of drugs. Finally, the integrated ADR data is then transmitted through Viggi Flow interface into the UMC adverse reaction database where signal processing can be carried out. There is a quality review panel which ensures the quality of ADR data that has been constituted for maintaining quality assurance in the program. All the centers will be assessed based on performance metrics criteria, completeness of reports, training imparted, and other parameters mentioned in the PV program protocol [20].

CONCLUSION

Pharmacovigilance plays a crucial role in ensuring the safety of pharmaceuticals by monitoring, assessing, and preventing adverse effects. Continuous vigilance and robust reporting systems are essential for identifying and managing potential risks associated with medications, ultimately contributing to public health and patient well-being. Collaboration between healthcare professionals, regulatory agencies, and the pharmaceutical industry remains essential for fostering a robust and proactive pharmacovigilance framework. The PVPI is organized at IPC through NCC under the direction of the Indian Government to produce independent data on drug safety that would be in line with international standards for drug safety monitoring. The comprehensive collecting and analysis of ADR data that results in timely alarms and measures to safeguard public health is a task for which national and regional PV systems are well-suited organizations. But the pharmacovigilance system in India is still not well developed. Disfavor of recent implementation of a well-structured pharmacovigilance program in India in accordance with the objectives and recommendations of WHO by CDSCO, desired success is still a distant dream. However increased awareness and training of public and medical professions, framing of strong regulations for reporting of ADRs, effective implementation and collaborative efforts between government, regulatory officials, pharmaceutical companies, health care

professionals and patient may lead to an effective pharmacovigilance system in India to insure the availability of safe medicines to public.

CONFLICT OF INTERESTS

The authors declare no conflict of interest

ETHICS APPROVAL: Not applicable

FUNDING

This study received no specific funding from public, commercial, or not for profit funding agencies.

AI TOOL DECLARATION

The authors declare that no AI and related tools are used to write the scientific content of this manuscript.

DATA AVAILABILITY

Data will be available on request

REFERENCES

- [1] Robb MA, Racoosin JA, Sherman RE, Gross TP, Ball R, Reichman ME, Midthun K, Woodcock J. The US Food and Drug Administration's Sentinel Initiative: expanding the horizons of medical product safety. *Pharmacoepidemiology and drug safety*. 2012 Jan 1;21(1):9.
- [2] Waller PC, Evans SJ. A model for the future conduct of pharmacovigilance. *Pharmacoepidemiology and drug safety*. 2003 Jan;12(1):17-29.
- [3] Bate A, Evans SJ. Quantitative signal detection using spontaneous ADR reporting. *Pharmacoepidemiology and drug safety*. 2009 Jun;18(6):427-36.
- [4] Kumar S, Baldi A. Pharmacovigilance in India: perspectives and prospects. *Journal of Drug Delivery and Therapeutics*. 2013 Aug 11;3(4):237-46.
- [5] Tripathy NR, Basha S, Jain R, Shetty S, Ramachandran A. Exenatide and acute pancreatitis. *J Assoc Physicians India*. 2008 Dec 1;56(6):987-8.
- [6] Palanisamy S, Kottur SG, Kumaran A, Rajasekaran A. A study on assessment of knowledge about adverse drug reactions. *Der Pharmacia Lettre*. 2013;5(1):41-52.
- [7] Moore N, Lécointre D, Noblet C, Mabilille M. Frequency and cost of serious adverse drug reactions in a department of general medicine. *British journal of clinical pharmacology*. 1998 Mar; 45(3):301-8.
- [8] Griffin JP. The evolution of human medicines control from a national to an international perspective. *Adverse drug reactions and toxicological reviews*. 1998 Mar 1; 17(1):19-50.
- [9] Von NC, Schwappach DL, Koeck CM. 2003. The epidemiology of preventable adverse drug events: A review of literature. *Wien Klin Wochenschr*. 115(12), 407-15.
- [10] Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. *JAMA*. 1998; 279: 1200-5.

- [11] Wester K, Jönsson AK, Spigset O, Druid H, Hägg S. Incidence of fatal adverse drug reactions: a population based study. *Br J Clin Pharmacol*. 2008; 65: 573–9.
- [12] Aronson JK, Ferner RE. Joining the DoTS: new approach to classifying adverse drug reactions. *BMJ*. 2003; 327:1222–5.
- [13] Rommers MK, Teepe-Twiss IM, Guchelaar HJ. Preventing adverse drug events in hospital practice: an overview. *Pharmacoepidemiol Drug Saf*. 2007; 16:1129–35.
- [14] Avery AJ, Anderson C, Bond C, et al. Evaluation of patient reporting of adverse drug reactions to the UK ‘Yellow Card Scheme’: literature review, descriptive and qualitative analyses, and questionnaire surveys. *Health Technol Assess*. 2011;15:1–234.
- [15] Jones JK. Adverse drug reactions in the community health setting: approaches to recognizing, counseling, and reporting. *Fam Community Health*. 1982 Aug; 5(2): 58-67.
- [16] Ramakrishnaiah H, Krishnaiah V, Pundarikaksha HP, Ramakrishna V. A prospective study on adverse drug reactions in outpatients and inpatients of medicine department in a tertiary care hospital. *Int J Basic Clin Pharmacol*. 2015;4:515-21.
- [17] Vora MB, Trivedi HR, Shah BK, Tripathi CB. Adverse drug reactions in inpatients of internal medicine wards at a tertiary care hospital: A prospective cohort study. *J Pharmacol Pharmacother*. 2011;2(1):21-5.
- [18] Kathiria JM, Sattigere BM, Desai PM, Patel SP. A study of adverse drug reactions in patients admitted to intensive care unit of a tertiary care teaching rural hospital. *Int J Pharm Pharm Sci*. 2013;5(1):160-3.
- [19] Acharya T, Mehta D, Shah H, Dave J. Pharmacovigilance study of adverse cutaneous drug reactions in a tertiary care hospital. *Natl J Physiol Pharm Pharmacol*. 2013; 3: 75-81.
- [20] Chatterjee S, Ghosh AP, Barbhuiya J, Dey SK. Adverse cutaneous drug reactions: a one year survey at a dermatology outpatient clinic of a tertiary care hospital. *Indian J Pharmacol*. 2006; 38:429-31.